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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,569	08/13/2001	Enno Krebbers	BB-1344	2373

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,569	KREBBERS ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24 and 27-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 and 27-36* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The finality of the Office Action mailed 8/18/2005 is WITHDRAWN and is replaced with the non-final action below.

Claims 1-23 and 25-26 have been canceled. Claims 24 and 27-36 are pending and examined.

Rejection of Claims 24-25 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

Rejection of Claims 24 and 29-36 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 24-39 drawn to an isolated polynucleotide of SEQ ID NO: 5 encoding a viral movement protein of SEQ ID NO: 6, and vectors, constructs, cells, plants and methods therewith of this application. U.S. provisional application 60/128,092 disclosed SEQ ID NO: 1 a partial length polynucleotide of SEQ ID NO: 1 encoding a partial length amino acid of SEQ ID NO: 2 from maize. Further SEQ ID NO: 1 and 2 of 60/128,092 disclose sequences that do not share the exact same sequences from their analogous portions of SEQ ID NO: 5 and 6 of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated polynucleotide sequences that encode viral movement polypeptides having an amino acid sequence of at least 95% sequence identity to SEQ ID NO: 6.

Applicant describes isolated plant EST and contig polynucleotide sequences encoding putative plant viral movement proteins on page 4 of the specification and the prior art teaches the isolation of a polynucleotide encoding a plant homolog of a viral movement protein, CmPP16 from *curcurbita maxima* (pumpkin) using RT-PCR and southern hybridization techniques taught by Xoconostle-Cazares (see specification page 1).

Applicant does not describe isolated polynucleotide sequence encoding proteins having at least 95% sequence identity to SEQ ID NO: 6 that have viral movement protein activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of

cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of isolated polynucleotide sequences encoding proteins that have at least 95% sequence identity to SEQ ID NO: 6 and have plant viral movement protein activity. Applicants only describe isolated plant EST and contig polynucleotide sequences encoding putative plant viral movement proteins on page 4 of the specification. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of isolated polynucleotide sequences encoding proteins that have at least 95% sequence identity to SEQ ID NO: 6 and have plant viral movement protein activity. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for plant viral protein activity, it remains unclear what features identify a plant viral movement protein. Since the genus of isolated polynucleotide sequences encoding proteins that have at least 95% sequence identity to SEQ ID NO: 6 and have plant viral movement protein activity has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that are 95% complementary to SEQ ID NO: 6 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 6, as well as sequences encoding proteins having no known plant viral movement protein activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the

genus of plant viral movement proteins encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24 and 27-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant's claim to an isolated polynucleotide encoding a viral movement protein wherein the polypeptide has an amino acid sequence that has at least 95% sequence identity to SEQ ID NO: 6 is based on the degree of DNA sequence and protein sequence identity with DNA isolated from rice in fungal elicitor experiments that showed induction of specific DNA expression wherein the encoded proteins showed homology for GenBank Accession AAC35866 also GI: 3603473; 16 September 1998 is not a specific and substantial asserted utility.

Computer analysis of genome sequences is currently one of the essential steps for obtaining functional and structural information about the respective gene products, but there are a number of inaccuracies that have been documented by researchers in the field. To illustrate the difficulties, Doerks *et al.*, (TIG, 1998, Vol. 14, No. 6; pp. 248-250; see pg 248, right column, 2nd paragraph) produces a table of BLAST results from an uncharacterized protein family that includes quite a few proteins with annotations. They state "Only one can give a clue about functional features; others are simply wrong, misleading or uninformative". He continues, "There were even examples in which homologues scored best in PSI-BLAST that did not have

the same catalytic activity". It is well established that sequence similarity is not sufficient to determine functionality of a DNA coding sequence. Doerks T. *et al.* state that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). In addition, Smith T. *et al.* (Nature Biotechnology, November 1997, Vol. 15; pp. 1222-1223) teach "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner S. *et al.* (TIG, April 1999, Vol. 15, No. 4; pp. 132-133) discusses the problem of inferring function from homology, stating "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Bork P. *et al.* (TIG, October 1996, Vol. 12, No. 10; pp. 425-427) discussing the same topic state " search methods are stretched and spurious hits are taken as real. Moreover, similarities might only be restricted to certain domains, but the function is transferred to a whole protein" (pg 426, right column, 1st paragraph). In addition, Venter C. *et al.*, (Science, 2001; Vol. 291, pp. 1304-1351) state on page 1334 last column to page 1335 column 3, that prediction of gene function with respect to assignment of function using predictive algorithms produces results replete with false positives. The problem of assigning function from structure is further exacerbated by the fact that the prior art does not support a correlation between the structure of the nucleic acids of the claims and the claimed function of the invention. Kim teaches GenBank Accession AAC35866 also GI: 3603473 an isolated sequence from rice wherein the protein has been identified as a plant fungal elicitor responsive protein (GenBank Accession AAC35866 also GI: 3603473; 16 September 1998) that has at least 90% sequence

identity to SEQ ID NO: 6 (specification Table 4, line 3). There is no data demonstrating that the polynucleotide sequence encodes a protein having the activity of a plant viral movement protein.

Furthermore, Applicant has not performed the most routine of scientific procedures known in the art, namely functional complementation of a mutant in yeast or some other organism or *in vitro* analysis to show utility of the claimed invention. Therefore, given the known errors inherent to functional genomics when relying solely on protein prediction programs, and the lack of quantifiable data demonstrating that SEQ ID NO: 5 encodes a plant viral movement protein of SEQ ID NO: 6, the credibility of the Applicant's specified utility for their invention is not supported in their specification.

Claims 24 and 27-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to isolated polynucleotide sequences that encode viral movement polypeptides having an amino acid sequence of at least 95% sequence identity to SEQ ID NO: 6.

Applicants teach isolation of polynucleotides from plants encoding putative plant movement proteins (See specification page 4 and in the Examples section).

Applicants do not teach that any of the isolated polynucleotides encode polypeptides that have plant movement protein activity.

The state-of-the-art does not recognize that one of skill in the art could predict which proteins encode a plant movement protein without resorting to undue trial and error experimentation. Moreover, the specification does not contain working examples of the claimed invention, including how to make polypeptides that have 95% sequence identity to SEQ ID NO: 6 by means specific additions substitutions, or deletions and that would have plant viral movement protein activity.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate and characterize a multitude of non-exemplified polynucleotides that encode polypeptides that have putative plant viral movement protein activity and characterize them in a host of non-exemplified transformed plants for a non-exemplified phenotype.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled

Claims 24 and 27-36 are rejected.

Claims 24 and 27-36 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a polynucleotide of SEQ ID NO: 5 encoding a protein of SEQ ID NO: 6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
November 8, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis